

REMARKS

Claims 1, 7-10, 14-20, 26-32, 38-40, and are pending. Claims 1, 8-10, 15-16, 26-27, 31-32 and 38 have been amended.

The issues outstanding in this application are as follows:

- Claims 1, 7-10, 14-20, 26-32 and 38-40 have been rejected under 35 U.S.C. §112, first paragraph, as not enabled by the Specification.
- Claims 8-10, 15 and 16 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite.
- Claims 1, 7-10, 14-19, 26-32 and 38-40 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Van Bree et al. (WO 01/72322).

I. 35 U.S.C. §112, first paragraph

Claims 1, 7-10, 14-20, 26-32 and 38-40 have been rejected under 35 U.S.C. §112, first paragraph, as not enabled by the Specification. Applicant has amended the claims. In view of these amendments, Applicants request that the rejection be withdrawn.

II. 35 U.S.C. §112, second paragraph

Claims 8-10, 15 and 16 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants have amended claims 8-10, 15 and 16. In view of these amendments, Applicants request withdrawal of the rejection.

III. 35 U.S.C. §103(a)

Claims 1, 7-10, 14-19, 26-32 and 38-40 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Van Bree et al. (WO 01/72322).

To establish a *prima facie* case for obviousness, all claim limitations must be found or suggested in the references cited or within the general knowledge in the art. Van Bree neither discloses nor suggests the N-terminal lactoferrin variants of the pending claims. *See* Van Bree, pg. 10 – pg. 11, line 3. Thus, Van Bree cannot support a *prima facie* case for obviousness for the pending claims.

The pending claims are also limited to lactoferrin compositions comprising at least 1% to at least 50% w/w of an N-terminal lactoferrin variants. Van Bree et al. does not disclose or suggest lactoferrin compositions comprising at least 1% to at least 50% w/w of an N-terminal lactoferrin variants.

The Examiner's reasoning to the contrary is misdirected. *See* Examiner's Office Action Dated 12/5/05, pg. 10, last paragraph. The Examiner cites the Specification for the definition of a "lactoferrin composition." This definition encompasses compositions of lactoferrin, N-terminal lactoferrin variants, or both. The Examiner then argues that the compositions of Van Bree meet the definition of a "lactoferrin composition." All of this is true. However, the limitation at issue is "at least 1% to at least 50% w/w of an N-terminal lactoferrin variant." As discussed in the previous response, Van Bree neither discloses or suggests such an element. This is a separate limitation which the Examiner must address to establish a *prima facie* case for obviousness.

In addition to finding a disclosure or suggestion of all claim limitations, a *prima facie* case for obviousness requires an established motivation to combine, or, as in this case, to modify a prior art reference. The Examiner must articulate the reasoning for the determination that one of skill in the art would be motivated to combine or modify the prior art. *In re Lee*, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002). The Examiner's attempts to offer a rationale for modifying Van Bree. In essence, the reasoning is that the method steps coincide with those in Van Bree. *See* Examiner's Office Action Dated 12/5/05, pg. 9, lines 5-14. This amounts to an argument that the

reference could be modified to the claimed methods. This alone is legally insufficient to establish a *prima facie* case for obviousness. See MPEP 2143.01 (Section III); *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990). The Examiner cannot rely on the skill in the art to supply a motivation to modify. See MPEP 2143.01 (Section IV); *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000).

Because, the Examiner has not established a *prima facie* case for obviousness, Applicants request that the rejection be withdrawn.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02703US2 from which the undersigned is authorized to draw.

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Respectfully submitted,

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